

Exhibit 5

**Investigation Report
of the
Special Demand Committee**

Board of Directors of Cardinal Health, Inc.

April 12, 2013

***Confidential
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EXECUTIVE SUMMARY

In Fall 2012, the Board of Directors (the “Board”) of Cardinal Health, Inc. (“Cardinal Health” or the “Company”) received a letter purporting to be a shareholder demand pursuant to Ohio Rev. Civ. P. 23.1, *et seq.* (the “Demand Letter” or the “Letter”). The Letter asserts that the Immediate Suspension Order that the Drug Enforcement Agency (the “DEA”) issued to the Company in February 2012 (the “2012 ISO”) was the result of a failure by the Company “to implement systems to detect and prevent the diversion of controlled substances into the illegal market.” (Demand Letter at 1.) Further, the Letter alleges that the Directors and Officers of the Company breached their fiduciary duties when they “knowingly and/or recklessly failed to establish” such a system, in violation of the Controlled Substances Act and the Memorandum of Agreement between the Company and the DEA in 2008 (the “2008 MOA”). (*Id.* at 10.)

On November 2, 2012, the Board appointed a special demand committee (the “Special Committee” or the “Committee”) to investigate and evaluate the Demand Letter. The Special Committee is composed of the two most recent additions to the Board, Clayton M. Jones, who has been a Director since September 2012 and is not named in the Demand Letter, and Dave P. King, who has been a Director since September 2011. The Special Committee retained Milbank, Tweed, Hadley & McCloy LLP (“Milbank”) to assist with the investigation. **Milbank collected and reviewed over 15,000 pages of relevant material dating from as early as 2005 to as late as 2012. Milbank also conducted interviews of twenty Company employees, two Audit Committee members, and counsel for the shareholder. Thirteen of the interviews were conducted in person and ten were conducted by telephone, and the length of the interviews ranged from approximately one to three hours.** The Special Committee concludes that the document review and interview process was methodical and comprehensive.

Based on the information the Committee gathered during its investigation, and its understanding of the applicable law, the Committee does not believe that it is in the best interest of the Company to pursue claims for breach of fiduciary duty against the Directors and Officers of the Company, as requested by the Demand Letter. The investigation shows that the Board at all times acted diligently and in good faith to fulfill its duties to the Company and the Company’s shareholders.

A director will be liable for damages only “if it is proved by clear and convincing evidence . . . that the director’s action or failure to act involved an act or omission undertaken with deliberate intent to cause injury to the corporation or undertaken with reckless disregard for the best interests of the corporation.” Ohio Rev. Code § 1701.59(E). Directors satisfy their obligation to remain informed of the corporation’s activities if a reasonable information and reporting system exists within the company. *See In re Caremark Int’l Inc. Deriv. Litig.*, 698 A.2d 959, 970-71 (Del. Ch. 1996). Where a reporting system exists, “[d]irectors will be potentially liable for breach of their oversight duty only if they ignore ‘red flags’ that actually come to their attention, warning of compliance problems.” *Stanley v. Arnold*, No. 1:12-CV-482, 2012 WL 5269147, at *6 (S.D. Ohio Oct. 23, 2012) (quoting *Forsythe v. CIBC Emp. Private Equity Fund*, No. 657-N, 2006 Del. Ch. LEXIS 60, at *7 (Del. Ch. Mar. 22, 2006)).

Following the 2008 MOA, the Company implemented an extensive and robust system of internal controls to detect and report suspicious orders of controlled substances. The Company

hired new management with extensive regulatory and/or pharmaceutical experience, including a Chief Compliance Officer, a Senior Vice President of Quality and Regulatory Affairs, and a Vice President of Anti-Diversion, and built an anti-diversion group with experienced investigators, pharmacists, and analysts to review potential new customers and to monitor existing customers for risks of diversion. Further, the Company assigned “threshold” ordering volumes for each customer based on a statistical analysis of ordering data, and created an electronic monitoring system to track customers’ orders against their pre-assigned threshold limits. The Company continued to enhance the electronic monitoring system and the underlying data. In addition, the Company developed a model to evaluate existing customers against customers that had been terminated as posing unreasonable risks of diversion, and hired a University Professor to test the model. A centralized database was created to store and track data on customers and orders, thereby facilitating the monitoring and investigation process. The Company created extensive policies and procedures applying to anti-diversion personnel, as well as the sales force and personnel in the distribution centers, including procedures for vetting new customers and monitoring orders from existing customers. The Company administered general anti-diversion training to thousands of employees, as well as targeted training on the specific policies and procedures that applied to each job function. The Board was fully informed of the implementation of these anti-diversion measures, and received regular and detailed progress reports throughout the process.

There were no red flags that the Company’s new anti-diversion controls were inadequate. The general reaction to the 2012 ISO was surprise, for a number of reasons. Management and key anti-diversion personnel were of the impression that the anti-diversion system was meeting or exceeding the Company’s obligations to detect and report suspicious orders. The Company benchmarked the system against those of its competitors to the extent that it could, and hired outside consultants to test and improve upon the system. The Company received little, if any feedback from the DEA about the new system. As part of the 2008 MOA, the DEA visited the Company’s corporate headquarters in Dublin to review the new anti-diversion measures and inspected five distribution centers. Although the DEA identified some issues with one of these facilities, the Company rectified those issues and the DEA did not take any formal action. Moreover, the DEA conducted numerous routine inspections of these and other distribution centers from 2008 through the end of 2011, issued no negative findings regarding the anti-diversion controls in place at any of the facilities, and, during some of the inspections, made positive comments indicating that they were impressed, or at least satisfied with the compliance measures that were in place at the facilities. Management informed the Board of the successful inspections. Management also informed the Board of the results of the electronic monitoring system, in particular, the fact that it flagged thousands of orders and led the Company to terminate and report many customers, and reduce the volume of controlled substances being distributed to many other customers. The Board was also informed that enhancements to the system in 2011 increased the accuracy of the system and significantly reduced the number of “false positives,” or legitimate customers whose orders were flagged.

The Demand Letter fails to identify a single red flag following the 2008 MOA that would have indicated that the Company’s anti-diversion measures were inadequate. Instead, the Letter tries to draw a connection between the allegations that the DEA levied against the Company in the suspension orders and order to show cause it issued in 2007 and 2008 (the “2007/2008 Action”) and the allegations at issue in 2012. In other words, the events surrounding the

2007/2008 Action were the red flags that the anti-diversion measures were inadequate leading up to the 2012 ISO. The problem with this theory is two-fold. First, as discussed, the Company instituted an entirely new anti-diversion system following the 2007/2008 Action. The Lakeland, Florida distribution center that was suspended by the 2012 ISO, one of the facilities at issue in the 2007/2008 Action, had been reinstated in late 2008, and underwent a successful inspection by the DEA pursuant to the 2008 MOA in early 2009 and a successful cyclical inspection by the DEA in 2010. Second, the events at issue in the 2012 ISO were different from those at issue in the 2007/2008 Action. The 2012 ISO involved the sale of oxycodone, while the 2007/2008 Action involved the sale of hydrocodone. In addition, the pharmacies at issue in the 2012 ISO were different from those at issue in 2007/2008 Action. Lastly, the 2012 ISO apparently stemmed from an unannounced shift by the DEA to a strict emphasis on volume, both for retail independent pharmacies, as well as for chain pharmacies.

Moreover, the facts surrounding the pharmacies at issue in the 2012 ISO make clear that the Company's anti-diversion system did not fail, but largely succeeded. Indeed, the electronic monitoring system alerted personnel to the increased orders from each of the four pharmacies at issue in the 2012 ISO, and at least one investigator alerted his superiors to certain indicators of diversion at the independent pharmacies. Certain individuals decided not to terminate those pharmacies for a time. Ultimately, the Company terminated the two independent pharmacies as customers, and significantly decreased its shipments of oxycodone to the two chain pharmacy stores at issue, months before the 2012 ISO.

The factual and legal deficiencies in the proposed action make it reasonably likely that the action would be dismissed before a decision on the merits, or that the action would conclude with a finding that the directors and officers fulfilled their fiduciary duties to the Company. The facts make clear that the Company implemented a robust system of internal controls to detect and report suspicious orders, and that the Board was well-informed of those controls. The directors did not fail to act in the face of any red flags that the Company's anti-diversion controls were inadequate.

The Committee also concludes that a review of other factors supports its determination that litigation of the sort requested in the Demand Letter is not in the best interests of the Company. The Committee employed its business judgment to consider all of the corporate interests that may weigh in favor of pursuing the proposed action. The proposed action would be certain to consume tremendous Company resources, and would present a significant distraction for management and employees of the Company. In addition, it is likely that the Company would be obligated to indemnify the directors for their costs in defending against the proposed action, pursuant to the Indemnification Agreement that nearly all of the present and former directors signed, or the indemnification provision contained in the Restated Code of Regulations of Cardinal Health, Inc., which applies to the remainder of the directors. The Committee finds that the expense of reimbursing the directors for litigation costs weighs against accepting the demand to pursue claims with a limited probability of success.

For the foregoing reasons, the Special Committee recommends that the Company not pursue the action requested by the Demand Letter.

REPORT OF THE SPECIAL DEMAND COMMITTEE

I. THE DEMAND

A. Allegations

On September 28, 2012, Faruqi & Faruqi, LLP sent a letter purporting to be a “Shareholder Demand Pursuant to Ohio R. Civ. P. 23.1, *et seq.*” (the “Demand Letter” or the “Letter”) on behalf of Isabelle Rauch, a purported shareholder of Cardinal Health, Inc. (“Cardinal Health” or the “Company”), to George S. Barrett, Chairman of the Board of Directors (the “Board”) of the Company. The Letter alleges that the Order to Show Cause and Immediate Suspension of Registration issued by the Drug Enforcement Agency (the “DEA”) in February 2012 regarding the Company’s Lakeland, Florida distribution center (the “2012 ISO”) was the result of a failure by the Company “to implement systems to detect and prevent the diversion of controlled substances into the illegal market” in accordance with the Controlled Substances Act (the “CSA”), the Memorandum of Agreement entered with the DEA in 2008 (the “2008 MOA”), and DEA “directives.”¹ (Demand Letter at 1, 10.) Further, the Letter alleges that certain “Directors and Officers,” defined as twenty-two present and former directors, “breached their duties of loyalty and care when they knowingly and/or recklessly failed to establish” such a system of internal controls. (*Id.* at 10.)

About four pages of the ten-page letter describe the three Orders to Show Cause and Immediate Suspensions of Registration issued against the Company in 2007 (the “2007 ISOs”), the Order to Show Cause issued in 2008 (together with the 2007 ISOs, the “2007/2008 Action”), the Memorandum of Agreement entered into with the DEA in 2008 (the “2008 MOA”), and the civil penalty levied in connection with the 2008 MOA. (*Id.* at 2-5.) The Letter details the DEA’s allegations in the 2007/2008 Action that the Company distributed excessive quantities of hydrocodone and failed to maintain effective controls against diversion at seven of its twenty-seven distribution centers. (*Id.*) As further described in the Letter, the Company agreed to “maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations.” (*Id.* at 4.) The Letter then discusses the 2012 ISO issued in connection with the Lakeland, Florida facility, one of the facilities that was suspended in 2007, and the DEA’s allegation that the Lakeland facility distributed excessive volumes of oxycodone to four Florida pharmacies despite “warning signs,” and thus did not have adequate controls in place. (*Id.* at 5-8.) According to the Letter, “[i]t was widely reported that the Company’s failure to comply with the 2008 MOA was at least a partial basis for the 2012 ISO.” (*Id.* at 7 (citing Declaration of Michele M. Leonhart, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 24, 2012) (“Leonhart Decl.”), ¶ 18 (“Although the drugs

¹ As will be discussed, the CSA requires Cardinal Health, as a distributor of controlled substances, to operate a system to detect suspicious orders of controlled substances, and further requires the Company to report such orders to the DEA. (*See infra* Part IV.B.3.c.) As part of the 2008 MOA, the Company agreed, among other things, to implement a system in which “[o]rders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purpose of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels.” (2008 MOA at 3.)

and the end customers were different, the common thread was Cardinal Lakeland's inadequate anti-diversion measures. The results of the recent investigation strongly indicated to me that, contrary to its promises in the 2008 MOA, Cardinal had not maintained adequate anti-diversion measures at its Lakeland facility.")).)

The Letter claims that, as a result of the 2012 ISO, the Company "has and will continue to suffer significant harm and incur substantial costs, including, but not limited to, potential fines, attorneys' fees, consulting fees, loss of business, and reputational harm," as well as damage to the Company's "corporate image and good-will." (Demand Letter at 9.) Finally, the Letter demands that the Board "take action against the Directors and Officers to recover the damages described herein for the benefit of the Company." (*Id.* at 10.)

B. Formation of Special Demand Committee

On November 2, 2012, the Board appointed a special demand committee (the "Special Committee" or the "Committee") to investigate and evaluate the Demand Letter. **The Special Committee is comprised of the two most recent additions to the Board, Clayton M. Jones, Director since September 2012, and Dave P. King, Director since September 2011.** Mr. Jones, who is not named in the Demand Letter, is Chairman and Chief Executive Officer of Rockwell Collins, Inc., an aviation electronics and communications equipment company, and is a Director of Deere & Company, an agricultural and construction machinery manufacturer. Mr. King is President, Chief Executive Officer, and Chairman of Laboratory Corporation of America Holdings, an independent clinical laboratory company. After receiving proposals from four law firms, and interviewing two firms, the Special Committee retained Milbank, Tweed, Hadley & McCloy LLP ("Milbank") to assist with the investigation.

II. RELEVANT LEGAL STANDARDS

Ohio law provides that "[a] director shall be liable in damages . . . only if it is proved by clear and convincing evidence . . . that the director's action or failure to act involved an act or omission undertaken with deliberate intent to cause injury to the corporation or undertaken with reckless disregard for the best interests of the corporation." Ohio Rev. Code § 1701.59(E). Directors satisfy their obligation to remain informed of the corporation's activities if an information and reporting system exists within the company that will provide senior management and the directors with accurate and timely information "sufficient to allow . . . informed judgments concerning . . . the corporation's compliance with [the] law" *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959, 970-71 (Del. Ch. 1996).² Where a reporting system exists, "[d]irectors will be potentially liable for breach of their oversight duty only if they ignore 'red flags' that actually come to their attention, warning of compliance problems." *Stanley*, 2012 WL 5269147, at *6 (quoting *Forsythe v. CIBC Emp. Private Equity Fund*, No. 657-N, 2006 Del. Ch. LEXIS 60, at *7 (Del. Ch. Mar. 22, 2006)). Accordingly, "with an effective compliance system

² "The law does not presume that the directors of a large organization like Cardinal Health are aware of every action by every employee or every sale to every customer." *Stanley v. Arnold*, No. 1:12-CV-482, 2012 WL 5269147, at *6 (S.D. Ohio Oct. 23, 2012) (citing *Caremark*, 698 A.2d at 971 ("[O]f course, the duty to act in good faith to be informed cannot be thought to require directors to possess detailed information about all aspects of the operation of the enterprise . . .")).

in place, corporate directors are entitled to believe that, unless red flags surface, corporate officers and employees are exercising their delegated corporate powers in the best interest of the corporation.”³ *Forsythe v. ESC Fund Mgmt. Co. (U.S.)*, No. Civ. A. 1091-VCL, 2007 WL 2982247, at *7 (Del. Ch. Oct. 9, 2007).

III. THE INVESTIGATION

A. Document Collection and Review

Milbank worked closely with the Company to collect documents relevant to the allegations contained in the Demand Letter, including documents relating to the Company’s anti-diversion policies and procedures, as well as communications and materials provided to the Board and the Audit Committee about those policies and procedures. The Company cooperated with the investigation fully and at all times. In total, Milbank collected and reviewed over 15,000 pages of relevant material dating from as early as 2005 to as late as 2012. These documents included Standard Operating Procedures (“SOPs”) and handbooks relating to anti-diversion measures, internal Company training materials, corporate governance guidelines and charters, and organizational charts. Milbank also reviewed the extensive court filings and accompanying exhibits from the 2012 proceedings with the DEA before the Administrative Law Judge, the District Court for the District of Columbia, and the United States Court of Appeals for the District of Columbia, as well as court filings and exhibits from the three derivative actions filed against the Board in May and June 2012. In addition, Milbank reviewed all Board and Audit Committee minutes from late 2007 to early 2012, as well as materials and communications conveyed to the Board and the Audit Committee during that time and relating to anti-diversion and other DEA-related issues, such as slide decks, reports, memoranda, and emails.

A team of Milbank attorneys reviewed each document to determine its significance to the investigation. The Special Committee concludes that Milbank’s document collection and review was thorough and systematic.

B. Interviews

Milbank conducted interviews of twenty Company employees and two Audit Committee members. Milbank worked closely with the Company to identify the types of employees who would be most directly involved with anti-diversion measures, and to compile a representative group of such employees. Specifically, Milbank interviewed the following Company personnel: one salesperson (Thomas Convery); one analyst in Quality and Regulatory Affairs (“QRA”) (Shirlene Justus); two pharmacists in QRA (Christopher Forst and Doug Emma); two compliance officers in QRA (Joyce Butler and Kay Gagliardi); two investigators in QRA (Vincent

³ “[C]ourts routinely reject the conclusion that because illegal behavior occurred, internal controls must have been deficient, and the board must have known so.” *Stanley*, 2012 WL 5269147, at *6 (citing *Desimone v. Barrows*, 924 A.2d 908, 940 (Del. Ch. 2007)); see also *In re Lear Corp. S’holder Litig.*, 967 A.2d 640, 653 (Del. Ch. 2008) (“[E]ven the most diligent board cannot guarantee that an entire organization will always comply with the law”); *Stone v. Ritter*, 911 A.2d 362, 373 (Del. 2006) (“[T]he directors’ good faith exercise of oversight responsibility may not invariably prevent employees from...causing the corporation to incur significant financial liability . . .”).

Moellering and Harvey Florian); both the current and former director of investigations (Ullrich Mayeski, a former regional director overseeing compliance officers, and Steve Morse, respectively); two senior vice presidents in the pharmaceutical distribution group (Steve Lawrence, for retail independent pharmacies, and Jim Scott, for national chain pharmacies); a Director of Operations Management for a distribution center (Scott McBride); Associate Chief Regulatory Counsel (Gary Cacciatore); Associate General Counsel (Michael Moné, the former Vice President of Anti-Diversion); the Chief Legal and Compliance Officer (Craig Morford); the Senior Vice President of QRA (Gilberto Quintero); the Vice President of QRA, Supply Chain Integrity (Todd Cameron); the Vice President of QRA, Pharmaceutical Distribution (Steve Reardon); and the Director of Operations and SOM Compliance (Nicholas Rausch). Corey Goldsand, in-house Counsel for the Company, was present as a facilitator for each of the interviews, but did not ask questions. Milbank also interviewed John Finn and Glenn Britt, of the Audit Committee, in the presence of Steve Falk, General Counsel, and counsel from Jones Day. Lastly, Milbank interviewed counsel for the shareholder, Lindsay Roseler and Michael Hynes, of Faruqi & Faruqi, LLP. Thirteen of the interviews were conducted in person, and ten of the interviews were conducted by telephone. The length of the interviews ranged from approximately thirty minutes to three hours, with most interviews lasting about one to two hours.

The purpose of interviewing upper-level management was to understand the Company's anti-diversion measures as they apply to those individuals and the individuals in their departments, how those measures changed since 2007 and the reasons for those changes, and how those changes were communicated to the Board. For lower-level employees, the goal of the interviews was to determine their knowledge of the anti-diversion policies and procedures as they apply to their job functions, how those policies and procedures evolved from 2007 through 2012, whether employees adhere to those policies and procedures in the day-to-day execution of their duties, and the effectiveness of training programs relating to anti-diversion. The purpose in interviewing the Audit Committee members was to verify that the Board and the Audit Committee were informed about the Company's anti-diversion measures, as well as any diversion problems or issues.

The Special Committee concludes that Milbank's interviews were comprehensive, both in terms of the topics addressed and the individuals who were interviewed.

IV. ANTI-DIVERSION POLICIES AND PROCEDURES

A. Anti-Diversion Measures Before the 2007 ISOs

In the years preceding the 2007 ISOs, the Company's anti-diversion measures focused mainly on preventing price diversion⁴ and diversion by internet pharmacies. There was a small group of employees involved in anti-diversion measures, including a Vice President of QRA, a QRA director, and employees at each division who were responsible for some compliance-related tasks, in addition to non-compliance responsibilities.

⁴ "Price diversion" refers to the practice of non-retail pharmacies purchasing pharmaceuticals from a wholesaler at contract or discount prices, and then reselling the pharmaceuticals at higher prices on the open market.

During this time, there was no electronic system for analyzing orders. The Company relied on sales data from the previous month, and thus there was a thirty-day lag time for information. In addition, most of the files on customers and orders were on paper, rather than electronic, and located in various places. In August 2005, Cardinal Health met with the DEA to discuss internet pharmacies and the DEA provided the Company with monthly dosage unit quantities for hydrocodone, phentermine, and alprazolam to assist with monitoring for internet pharmacy activity. The Company implemented a system to review customer orders based on that data, and also provided the information to sales personnel. Further, each division provided a monthly Ingredient Limit Report to the DEA, which identified customers whose monthly purchase quantities exceeded certain predetermined amounts. (Required Reports to DEA, June 15, 2006, at 6.) In addition, employees in the distribution centers were expected to identify and report suspicious or excessive purchases of controlled substances to their superiors.

The evaluation of new customers during this time focused on whether the pharmacy allowed customers to order prescriptions over the internet or filled prescriptions for customers of other internet pharmacies. (Internet Pharmacies: Customer Approval and Oversight Policy, Apr. 13, 2007, at 1.)

During Spring and Summer 2006, there were live training sessions for employees at six locations around the country, focused primarily on price diversion and diversion by internet pharmacies. The Company also developed and implemented two mandatory computer-based trainings in August and December 2007 for all sales personnel and field operations managers, which also focused on internet pharmacy diversion.

B. Anti-Diversion Measures from the 2007 ISOs through the 2012 ISO

Before 2007, the DEA's enforcement efforts seemed to be primarily aimed at internet pharmacies. The 2007/2008 Action signaled to the Company that the DEA's enforcement efforts had expanded to include distributors, particularly with respect to sales to retail independent pharmacies affiliated with internet pharmacies. In response to the 2007/2008 Action, and in an attempt to try to anticipate the DEA's next area of focus, the Company set out to build a new anti-diversion program. Over time, the Company added more than forty positions and invested approximately \$25 million in the new system. (Declaration of Craig Morford Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA Administrative Law Judge ("ALJ") Apr. 12, 2012) ("Morford Decl."), ¶¶ 5, 7.)

In December 2007, the Company hired Michael Moné as Vice President of Anti-Diversion, within QRA. (Amended Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 6, 2012) ("Feb. 6 Moné Decl."), ¶ 3.) Moné was a pharmacist and an attorney, whose prior experience included representing the Board of Pharmacy as counsel with the Florida Department of Professional Regulation, representing the Boards of Chiropractic, Osteopathic Medicine, and Veterinary Medicine as Assistant Attorney General in Florida, and acting as Executive Director of the Kentucky Board of Pharmacy. (See *id.* ¶ 2.) One of Moné's first actions was to build out the anti-diversion group. In February and March 2008, Moné hired Steve Morse and Christopher Forst, both pharmacists, as Directors of Supply Chain Integrity. Morse hired four investigators, whom he would oversee in conducting investigations and site visits of customers. Forst would handle the

pharmaceutical analysis of customers, and would later hire two additional pharmacists to assist with that review. Nicholas Rausch, a consultant with the Company who assisted with the early investigations of customers, was brought in to the anti-diversion group in 2007 as a Manager of Supply Chain Integrity. Rausch, who was later promoted to Director, would oversee the New Account Specialists, or “analysts,” and would be responsible for the development and implementation of an electronic monitoring system. In addition, the Company hired twenty-four compliance officers, who would be based at the Company’s distribution centers and would oversee various compliance measures, including the anti-diversion measures applying to distribution centers. The compliance officers would be part of the QRA group and would report to Steve Reardon, Vice President of QRA, via regional directors.

In May 2008, the Board brought in a new Chief Compliance Officer, Craig Morford, with a mandate to establish a premier anti-diversion system. Morford had extensive leadership and regulatory experience, as a former U.S. Attorney for the Middle District of Tennessee and the Eastern District of Michigan and the former Acting U.S. Deputy Attorney General, overseeing the various U.S. Attorney offices and agencies within the Justice Department. (Morford Decl. ¶ 2.) In 2009, the Company hired Gilberto Quintero as the new Senior Vice President of QRA, reporting directly to Morford. (Declaration of Gilberto Quintero Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 13, 2012) (“Quintero Decl.”) ¶ 4.) Quintero came to the Company with extensive experience in regulatory and compliance issues from his former role at Wyeth Pharmaceuticals. (*Id.* ¶ 3.)

The Company set a strong tone that anti-diversion was the responsibility of every employee. (Morford Decl. ¶ 5.) By the end of 2008, the Company had begun implementing a host of new policies and procedures designed to detect and report suspicious orders. In particular, the Company implemented detailed procedures for reviewing potential new customers and for monitoring existing customers. The procedures for reviewing potential new customers would apply to the anti-diversion group, as well as the salespeople in the field. (Suspicious Order Monitoring Presentation, Feb. 2009, at 7-10.) The monitoring of existing customers would involve the creation of a new electronic monitoring system (at times referred to as the “Suspicious Order Monitoring” or “SOM” system), as well as specific duties for the anti-diversion group, the salespeople, and the employees at the distribution centers. (*Id.* at 7-14.) The Company administered extensive mandatory training on the anti-diversion policies and procedures. (*Id.* at 15-16.) The Company hired consultants to review and test the anti-diversion system, and tried to gauge the DEA’s response to the system in communications with DEA personnel and by carefully observing the DEA’s cyclical inspections of distribution centers.⁵

1. Review of Potential New Customers

In January 2008, the Company issued standard operating procedures (“SOPs”) that required the anti-diversion group to evaluate any potential new retail independent customer to

⁵ The DEA conducts routine cyclical inspections (sometimes referred to as “audits”) of manufacturers and distributors of controlled substances and regulated chemicals.

determine whether it posed a risk of diversion.⁶ (New Retail Independent Customer Survey Process (“New Customer Survey Process”), Jan. 4, 2008, at 1-2; New Account Approval, Dec. 22, 2008, at 1; *see also* Suspicious Order Monitoring Presentation, Feb. 2009, at 10; Quality and Regulatory Affairs: Overview of Anti-Diversion Program, 2011, at 5.) The procedures required salespeople, in conjunction with the potential new customer, to complete a New Retail Independent Pharmacy Questionnaire, commonly referred to as a “Know Your Customer”⁷ questionnaire (the “New Customer Questionnaire”). (New Customer Survey Process, at 1.) The New Customer Questionnaire required information about the pharmacy’s business, including the pharmacy’s DEA and state licenses, whether there were any prior disciplinary actions, such as revocation or suspension of licenses, the method by which the pharmacy received prescriptions, whether the pharmacy filled prescriptions for out of state patients, the pharmacy’s expected usage for certain products, and whether there were any local pain or weight loss clinics in the area and the proximity of any such clinics. (*See* New Customer Questionnaire, Jan. 4, 2008.) The procedures also required the salespeople to take photos of the interior and exterior of the pharmacy and to send the photos to the anti-diversion group for review. In addition, all new retail independent customers were required to sign a DEA compliance agreement titled, “Compliance Representations and Warranties for Pharmacy Customers.” (New Customer Survey Process, at 2.)

The anti-diversion group was responsible for the review and analysis of potential new accounts. (New Account Approval, Dec. 22, 2008, at 1.) In 2010, three analysts were hired to focus on reviewing potential new accounts. The analysts reviewed the New Customer Questionnaires to verify the information that the customer provided and look for common indicia of diversion, such as high percentage of cash payments, unjustifiably high percentage of controlled substance sales, and out-of-state patients or prescribers. (*See* New Customer Survey Process, at 2; Declaration of Nicholas Rausch Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 13, 2012), ¶ 11.) If there were any concerns, a pharmacist in the anti-diversion group would review the data on the potential new customer and decide whether to open the account, refer the case for additional investigation, or decline the account. (Feb. 6 Moné Decl. ¶ 12.)

For new chain pharmacy customers, the Company would obtain information about the chain’s number of stores, anticipated usage, and internal anti-diversion procedures. (Feb. 6 Moné Decl. ¶ 13.) If a chain sought to open a new pharmacy, the corporate office would need to provide Cardinal Health with the new pharmacy’s state license and DEA registration. (*Id.* ¶ 14.)

⁶ Regarding the SOPs generally, the actual practices were constantly being improved or modified, and those changes would be reflected in subsequent versions of the SOPs. With respect to the New Customer Survey Process, a revised version was issued in October 2009.

⁷ “Know Your Customer” or “KYC” is a term used within the Company to refer to the diligence measures for reviewing and monitoring potential and existing customers.

2. Monitoring Existing Customers

a. Electronic Sales Monitoring

In 2007, the Company began building out the technology and infrastructure for an electronic system that would store data about customers and monitor orders. At that time, the Company's data on customers was located in various places and largely on paper. Further, there was no analytical capability or real-time data for reviewing orders. Moné and Rausch worked with the Company's IT group to build the electronic monitoring system. The system was built on top of the order fulfillment system, so that it could draw from the data in the order fulfillment system.

In late 2007 through early 2008, the Company implemented the basic components of the electronic monitoring system. The Company engaged Deloitte to help develop the analytical methodology for setting thresholds. In 2008, Moné and Rausch began conducting informal "benchmarking" of the electronic monitoring system, engaging in arms' length communications with other distributors about their respective systems. Those efforts continued through the years.

In 2010, the Company partnered with IBM to create Anti-Diversion Centralization ("ADC"), a central repository that allowed all data on a particular customer to be stored and accessible on a single platform. (Quintero Decl. ¶ 7.) The new system made the process of reviewing customers much easier, both for pharmacists reviewing orders and for investigators preparing for site visits, because all of the data on customers was captured in one place. In addition, ADC provided a better sense of the "whole picture," showing more comprehensive and detailed information about the customer. The program showed all of the information that had been collected about the customer, prior held orders, communications about prior held orders, and graphs depicting previous orders and fluctuations in orders, all of which assisted pharmacists in reviewing orders. ADC also captured the pharmacists' decisions about whether to release the order and allow it to be filled or to delete the order and not allow it to be filled.

(i) Setting Thresholds

When the electronic system was created in 2008, thresholds were set by identifying a "baseline" drug quantity for one month, using the mean volume for each drug family for each class of trade. The customers were segmented into four main classes of trade: retail independents, chains, hospitals, and long-term care.⁸ The stores were segmented by size (small, medium, and large) and thresholds were set for each size category using multiples of 3, 5, or 8, depending on the drug family, based in part on multiples that the DEA had previously provided

⁸ The system first focused on the four highest risk drugs and on retail independent pharmacies, because those were the pharmacies at issue in the 2007/2008 Action and were thought to pose the highest risk of diversion. As 2008 progressed, the remaining 106 drugs were included and the system was expanded to include long-term care, then hospitals, and then chain pharmacies.

for certain combination products⁹ containing those controlled substances. Thus, the system was designed to create an “alert” if the volume for a particular store exceeded the assigned threshold.

If a new retail independent pharmacy provided ordering and dispensing information, a pharmacist would create a customized threshold for the pharmacy, taking into account the size and location of the pharmacy, its history of dispensing, the normal wholesale package size of drugs ordered, the number of different strengths within a given family of controlled substances, the availability of generic drugs for the controlled substances, and whether the pharmacy used automated dispensing. (Feb. 6 Moné Decl. ¶ 16.) SOPs issued in December 2008 outlined the specific steps for calculating thresholds: (1) extract and formulate a list of customers that have purchased monitored items and historical sales data for those customers for all monitored items; (2) differentiate customers through segmentation by size and/or specialty; (3) evaluate historical controlled substance sales data per drug family, per month for each customer segment to establish appropriate threshold limits, using the multiples of 3, 5, or 8; (4) incorporate background information about the pharmacies to establish final threshold limits; and (5) apply rounding logic and finalize threshold limits.¹⁰ (Process to Establish SOM Threshold Limits, Dec. 22, 2008, at 2-4.) Thus, a baseline was first established for all “monitored items,” which included any controlled substances. (*Id.* at 1.) The baseline was then adjusted up by a statistically significant factor or variable to formulate the threshold limit for the pharmacy. (*Id.*) If a new retail independent pharmacy did not provide dispensing data, the pharmacy would receive the mid-level threshold limit. (Feb. 6 Moné Decl. ¶ 16.) The Company did not inform customers of their threshold limits. (*Id.*)

Thresholds for new chain stores were based on a standard threshold for the entire chain, because chain stores usually have a known ordering pattern for the majority of stores. (*Id.* ¶ 17.) The Company also took into account the chain’s anti-diversion measures in setting thresholds. (See Supplemental Declaration of Nicholas Rausch Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 23, 2012) (“Rausch Supplemental Decl.”), ¶ 5.)

(ii) Monitoring Thresholds

In the beginning, the system was primarily focused on volume, and whether the order was more than two standard deviations away from the mean. As it evolved, it looked at other metrics, many of which were based on guidance that the DEA provided in letters to distributors and manufacturers, such as the ratio of controlled to non-controlled substances and percentage of cash sales. As the system progressed further, it incorporated regression analyses to review volatility, and the behavior of the individual customer. Thus, the flagging of an order for volume triggered a review of other data, such as order frequency and history.

⁹ The DEA provided guidance to chemical distributors approving the use of multiples of three and eight for drug products consisting of a listed chemical and a controlled substance. (See Drug Enforcement Administration Office of Diversion Control, “Knowing Your Customer/Suspicious Order Reporting,” http://www.deadiversion.usdoj.gov/chem_prog/susp.htm.)

¹⁰ Each of these steps included a number of sub-steps. A revised version of the Process to Establish SOM Threshold Limits was issued in January 2010.

In 2010, Quintero asked the Pricing Analytics group to develop a system to identify outlying customers. In 2011, the Company hired a full time statistician for the purpose of maintaining and enhancing the system. This individual was asked to analyze customers that had been terminated as posing unreasonable risks of diversion to determine if there were similarities in the buying patterns of these customers, both in terms of changes in volumes and combinations of drugs. In June 2011, the Company implemented a logistical regression model that compared those customers to existing customers. Thus, the system would flag independent pharmacies whose ordering patterns began to emulate the ordering patterns of customers previously terminated as posing risks of diversion, prompting additional investigation of the customer.¹¹ (Feb. 6 Moné Decl. ¶ 22.) The model was validated by the Chair of the Department of Integrated Systems Engineering of Ohio State University. (*Id.*)

The analysts in Rausch's group were responsible for monitoring threshold events. SOPs issued in December 2008 outlined the procedures for the daily reporting of threshold events within the Company.¹² (Daily Threshold Reporting, Dec. 22, 2008, at 1.) In addition, the electronic monitoring system would generate an early dialogue notice when a customer's order caused it to reach 75% of its monthly threshold. (Feb. 6 Moné Decl. ¶ 18.)

b. Monitoring by Salespeople

Salespeople were not usually aware of their customer's thresholds, but they were expected to monitor their customers using other methods. In 2008, the sales force started receiving "Highlight Reports," which were monthly reports that identified "Red Flag" or "Yellow Flag Customers" based on certain percentage increases in their controlled substance orders. (*See generally*, Sales – Highlight Report, Dec. 22, 2008.) SOPs issued in December 2008 required salespeople to visit their Red Flag Customers within ten working days to look for signs of diversion and complete an online Customer Visit form.¹³ (*Id.* at 3.) For Yellow Flag Customers, salespeople were required to contact the customer as soon as possible to understand the reason for the increased ordering and look for signs of diversion. (*Id.*) If the customer had been a Yellow Flag Customer for consecutive months, the salesperson or an investigator was required to visit the customer within fifteen business days. (*Id.*) In 2009, the SOPs were revised to define "Red Flag Customers" as customers whose orders of controlled substances or List 1 chemicals increased by 15% (where the increase was at least \$10,000), and "Yellow Flag Customers" as customers whose orders increased by 10% (where the increase was at least

¹¹ In or around June 2011, the Company also developed multiple linear regression models for chain pharmacies, based on the chains' buying patterns for certain classes of drugs.

¹² The SOPS provided that the IT department would send a report of the order to the anti-diversion group, which would record the order into a master file, create a customer profile to use during the review of the order, and create a "held order report." (Daily Threshold Reporting, Dec. 22, 2008, at 2-3.) The sales group would also be informed of the threshold event. (*Id.* at 4-5.) A revised version of the Daily Threshold Reporting SOP was issued in January 2010.

¹³ The Customer Visit form included the following questions, among others: whether there were people loitering or lined up at the pharmacy or local practitioner's office; whether the pharmacy had front-end or over-the-counter merchandise; whether there was a pain management or weight loss clinic located in the general vicinity of the pharmacy; and any other observations by the salesperson. (*See* Supply Chain Services Documentation of Customer Visit form.)

\$5,000).¹⁴ (Sales – Highlight Report, June 9, 2009, at 3.) The Highlight Reports were discontinued in or around late 2010, and eventually replaced by ordering data made available to salespeople directly through a program called “Winwatcher.” *See infra* Part VI.B.2.b.

Other SOPs issued in December 2008 required salespeople to perform an “early dialogue” with customers whose orders neared their threshold by a certain percentage. (Sales – Early Dialogue, Dec. 22, 2008, at 2.) The procedures required salespeople to contact the customer regarding its increase in ordering to determine whether there was a trend or data that explained the orders, such as seasonality, new business contracts, change in business model, purchase of files, or relocations. (*Id.*) The salesperson was required to document the relevant facts and complete a Customer Visit form. (*Id.* at 2-3.)

Salespeople were expected to visit their customers regularly and to look for signs of diversion on each visit. (See Suspicious Order Monitoring Presentation, Feb. 2009, at 8; Declaration of Jon Giacomini Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 12, 2012) (“Giacomini Decl.”), ¶ 10.) SOPs issued in December 2008 detailed the “process requirements for the continuous monitoring and reporting of customer order activities by [the sales force],” and listed “anti-diversion alert signals” for the sales force to be aware of when visiting customers.¹⁵ (Sales – Anti-Diversion Alert Signals, Dec. 22, 2008, at 1-2.) The alert signals included: pharmacies with minimal or no front end merchandise, little or no walk-in business, or primarily cash customers, or pharmacies soliciting buyers of controlled substances via the internet; orders containing a high percentage of controlled substances relative to non-controlled substances, or excessive quantities of a limited variety of controlled substances; and one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled. (*Id.* at 2.) The SOPs required the salesperson to complete an online Customer Visit form and to assess a risk level for the customer if two or more of the anti-diversion alert signals were present. (*Id.*)

As discussed above, salespeople were notified if one of their customers experienced a threshold event. (See *supra* note 12.) SOPs issued in December 2008 required the customer to complete a Threshold Event Survey.¹⁶ (Sales – Investigation, Dec. 22, 2008, at 2.) Following completion of the survey, the anti-diversion group might determine that a site visit was necessary and alert the salesperson, who might be asked to accompany an investigator on a site visit of the pharmacy. (*Id.* at 3.)

In 2008, the Company revised the compensation policies for salespeople, to encourage salespeople to report customers who may pose risks of diversion. In particular, the Company instituted a policy that if a customer was terminated as a diversion risk, the salesperson’s sales goals would be reduced by the portion attributable to that customer. (See Giacomini Decl. ¶ 12.)

¹⁴ The Sales – Highlight Report SOP was revised again in January 2010.

¹⁵ A revised version of these SOPs was issued in June 2009.

¹⁶ A revised version of these SOPs was issued in June 2009.

c. Monitoring at the Distribution Centers

Compliance officers and other employees at the distribution centers were also responsible for monitoring orders. SOPs issued in April 2009 required compliance officers to review monthly reports of the top twenty-five retail independent purchasers of commonly diverted drugs¹⁷ (“Top 25 Reports”), to identify customers of concern, and to participate in “ride alongs” with salespeople to visit customers of concern.¹⁸ (Compliance Officer: Duties and Responsibilities, Apr. 17, 2009, at 1.)

In addition, the supervisor in the cage/vault area, as well as at least one other employee in the cage/vault, were required to review “Large Order Reports,” which would identify all orders over a certain quantity (as identified by the anti-diversion group).¹⁹ (Cage/Vault SOM Process, Dec. 2, 2008, at 1.) The Large Order Reports would be reviewed before the orders were packaged to look for any “Orders of Interest,” defined as an order that appears to “significantly deviate” from the customer’s normal ordering pattern or the normal ordering pattern for the class of customer. (*Id.* at 1, 3.) Employees were instructed that Orders of Interest could exhibit the following traits, among others: quantity that was not normal for the customer or the customer’s class; substance that was not normal for the customer; quantity that has shown signs of a steady increase over time; or substance/quantity that did not match the season. (*Id.* at 3.) If any Orders of Interest were identified, the cage/vault supervisor, based on his or her knowledge or experience, could authorize the shipment or hold the order and not allow it to be filled. (*Id.*) If an order was held, the compliance officer and the anti-diversion group would be notified.²⁰ (*Id.*)

Orders of Interest could also be identified at any time during the processing and fulfillment of the order. The Company instituted a policy in 2008 that enabled any employee at a distribution center to “raise their hand” and hold an order if it looked unusual. (*See* Suspicious Order Monitoring Presentation, Feb. 2009, at 12; Declaration of Joyce R. Butler Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 12, 2012) (“Butler Decl.”), ¶ 13.) The employees in the cage and vault filled orders for the same customers on a regular basis, and thus were in a position to recognize when an order was unusual based on the size of the

¹⁷ The drugs included hydrocodone and oxycodone. Revised versions of these SOPs were issued in 2009 and 2010.

¹⁸ The requirement for compliance officers to participate in a certain number of ride alongs each year was eliminated in 2010, as it was considered not a good use of the Compliance Officers’ time. (*See* Compliance Officer: Duties and Responsibilities, Nov. 12, 2010, at 1.) Ride alongs are now used for training new hires.

¹⁹ Revised versions of the Cage/Vault SOM Process were issued on December 9, 2008, January 21, 2010, April 7, 2010, April 22, 2010, and August 3, 2010.

²⁰ The customer and the appropriate sales representative were also notified if an order was held at the distribution center. The relevant sales and management team would receive an email describing the held order the following morning.

order and the customer's ordering history. The employees were also trained to recognize indicators of diversion.²¹ *See infra* Part IV.B.4.b.

Orders of Interest were treated as threshold events and analyzed accordingly. (Cage/Vault SOM Process, Dec. 2, 2008, at 3.)

3. Responding to Threshold Events

a. Review of Threshold Events by Pharmacists

If a customer experienced a threshold event, i.e., when a customer's orders in a given month exceeded its threshold for a particular drug family, the order causing the overage and any subsequent orders would be held pending review. (Daily Threshold Reporting, Dec. 22, 2008, at 1.) A pharmacist would review the files on the customer and the information about the specific order. (*See* Rausch Supplemental Decl. ¶ 6.) The Company made a concerted effort to hire pharmacists with a variety of pharmaceutical backgrounds. Christopher Forst, Director of Pharmacy Assessment, had many years' experience as a hospital pharmacist. Two additional pharmacists were hired in 2010, with mail order and retail experience.

In December 2008, the Company issued detailed procedures for the review of threshold events. (*See generally*, Threshold Event Review, Self Verification; Decision Making and Threshold Outcome Communication, Dec. 22, 2008 (hereinafter, "Threshold Event Review").) Generally, the procedures required review of the customer's profile to determine the customer's business type, the distributor information (whether Cardinal Health was the primary or secondary distributor),²² the drug family that triggered the threshold event, the customer's total number of threshold events in general and for the specific drug family at issue, the customer's total current monthly accrual and monthly usage for the specific drug family, and the customer's monthly drug family limit. (*Id.* at 1-2.) The procedures then required review of the specific order to determine the type of drug family products in the held order, the quantity of drug family products in the held order, and the reasonableness of the total drug family order. (*Id.* at 6.) Next, the procedures called for certain decisions to be made by an individual with a degree in pharmacy, including: (1) whether the order was reasonable based on applied reasoning (looking at such factors as seasonal events, natural events, regional prescribing habits, the location of the pharmacy or facility in relation to health care providers, whether it was an end of month order, whether there was a shortage of other products, or whether the monthly limit was incorrect); (2) whether the order was excessive (for example, as a result of an order entry error or duplication); and (3) whether the order was suspicious (i.e., excessive in quantity, strength, or frequency, or an unexplainable deviation from the norm). (*Id.*)

²¹ Employees in the cage and vault undergo rigorous screening, training, and certification processes before they are granted access to controlled substances, in accordance with DEA requirements and detailed SOPs in existence since at least May 2008. (*See, e.g.*, Personnel, May 14, 2008; Employee Screening and Training Requirements for DEA Regulated Activities, May 8, 2009, and as revised, Mar. 17, 2010, June 3, 2011, and Feb. 4, 2013.)

²² Certain chains have their own warehouses and vaults for stocking drugs. For these chains, their primary source is their own warehouse system, and Cardinal Health acts as a secondary distributor, providing "back up" if the chain runs out of, or chooses not to stock, a particular drug.

When an independent retail pharmacy experienced a threshold event, a pharmacist could request that the investigator conduct a “deep dive” investigation of the pharmacy, which included a site visit of the pharmacy.²³ (*See* Threshold Event Review, at 18.) Investigators and pharmacists conducted occasional “surveillance” visits of chain pharmacies, during which they would visit the store without announcing their presence.

Distributors did not typically perform the same diligence on chain pharmacies as they did on retail independent pharmacies. (*See, e.g.*, DEA Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program, AmerisourceBergen Corp., Sept. 11, 2007, at 7; Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 13, 2012) (“Apr. 13 Moné Decl.”), ¶ 39.) The pharmacies at issue in the 2007/2008 Action were retail independent pharmacies, and chain pharmacies were generally believed to pose lesser risks of diversion than retail independent pharmacies. Pharmacists at chain stores usually do not share in the profits for the store, and chain pharmacies have their own anti-diversion and loss prevention systems.²⁴ (Feb. 6 Moné Decl. ¶ 10.) Cardinal Health communicated with the chain’s corporate offices to supply information regarding orders of concern. (Apr. 13 Moné Decl. ¶ 38.) If a chain pharmacy experienced a threshold event, the Account Manager would contact the chain’s corporate office to request information regarding the order at issue and then provide the information to the anti-diversion group for review. The anti-diversion group would review the data on the order and the proffered explanation for the threshold event and respond in one of the following ways: (1) accept the explanation and temporarily increase the threshold to ship the order; (2) accept the explanation and permanently increase the threshold; (3) ask for additional information; or (4) reject the explanation and refuse to ship the order.

If a pharmacist deemed an order reasonable, he or she could release the order and, if warranted, increase the threshold in the electronic system. (Threshold Event Review at 6; *see also* Quality and Regulatory Affairs: Overview of Anti-Diversion Program, 2011, at 6-7.) A pharmacist could determine that an order was reasonable for a number of reasons. For example, if a customer’s business model changed in a way that caused it to grow, an increase in ordering would be expected and the pharmacist might decide that an upward adjustment in the customer’s threshold was appropriate. If the pharmacist deemed the order unreasonable and suspicious, he or she would delete the order and not allow it to be filled.²⁵ (*Id.* at 6-7; *see also* Quality and Regulatory Affairs: Overview of Anti-Diversion Program, 2011, at 7.) The pharmacist’s decision to release the order and allow it to be filled or to delete the order and not allow it to be filled was documented within the electronic system. (Threshold Event Review, at 14.)

²³ In certain circumstances, pharmacists or analysts might conduct phone interviews of customers rather than conduct site visits.

²⁴ With respect to CVS in particular, Cardinal Health and CVS conducted a webinar in 2008 in which CVS discussed its loss prevention measures. (Apr. 13 Moné Decl. ¶ 83.)

²⁵ If the order was unreasonable but was the result of an entry error, the pharmacist would delete the order in the system and not allow it to be filled, but would not report the order. (*Id.*)

b. On-Site Investigations

The vast majority of on-site investigations were conducted in response to threshold events. Investigations would also be conducted at the request of Moné, based on information he received from his contacts in the pharmacy arena. As the electronic system became more advanced, the Company began to conduct proactive investigations in advance of threshold events.

In early 2008, the Company worked with Cedegim, a compliance consulting company, to set guidelines and processes for the investigators to follow. In December 2008, the Company issued detailed SOPs setting out the required procedures for conducting on-site investigations.²⁶ (On-Site Investigations, Dec. 22, 2008, at 1.) The investigations were comprised of four main components: initial case preparation; background investigation; site visit; and report preparation. (*Id.* at 5-11.) During the initial case preparation stage, the investigator would review the Company's existing files on the customer. (*Id.* at 5.) Based on this information, the investigator would develop a background research plan that included reviewing licensed customer information, threshold events, customer responses to questionnaires, and previous decisions regarding shipment to the customer. (*Id.*)

During the background investigation, the investigator would use various internet resources to verify the information in Cardinal Health's files and conduct the background research on the pharmacy, its employees, local physicians and healthcare facilities, and geographical information. (*Id.* at 6.) The investigator would research any disciplinary actions against the pharmacy or its owners or employees, and any civil or criminal actions taken against the pharmacy, its employees, local physicians, or any other person associated with the pharmacy. (*Id.*) The investigator would then contact an appropriate representative of the pharmacy to schedule and discuss the purpose of the visit. (*Id.* at 7.) The investigator would also contact the salesperson assigned to the licensed customer and offer him or her the opportunity to be present during the site visit. (*Id.*)

Upon entering the community and the vicinity of the pharmacy, the investigators were directed to observe and document the surroundings and to note any specifics relating to business practices, business volume, and business type, such as: the types and number of health care facilities located within the area; the types and number of medical practices, especially noting those who are characteristically heavy prescribers of controlled substances (e.g., pain clinics, orthopedics, surgeons, oncologists, cancer centers, weight loss clinics); unusually large numbers of individuals in the general vicinity of a physician's practice or the pharmacy; and whether the clientele was consistent with the demographics of the area. (*Id.* at 8.)

During the site visit, investigators were required to interview the appropriate personnel and to complete the data collection worksheet. (*Id.* at 7, 9.) Investigators were instructed to use the data collection worksheet as a guide and to be generally observant and particularly watchful for potential indicators of diversion, including: customers exhibiting drug-seeking behaviors; cars full of pharmacy customers; out-of-state license plates in the parking lot; long lines at the pharmacy; customers who appear to be from outside the reasonable drawing area for the facility;

²⁶ Revised versions of these SOPs were issued in November 2009, April 2012, and June 2012.

evidence of illicit drug use around the facility (e.g., used syringes, empty prescription containers); mailing materials or other evidence of operation of an internet pharmacy; high ratio of prescriptions for regulated drugs versus other drugs; high ratio of regulated prescription drug stock to other prescription drug stock; small or non-existent front end (non-prescription) drug stock; and primarily cash transactions for regulated drug prescriptions.²⁷ (*See id.* at 7-8.) Investigators were expected to request a tour of all areas of the facility and permission to take photographs of the front of the prescription department, the front end non-prescription drug sections, several prescription bays or shelves, the back room, any automation, and the front of the facility from the outside. (*Id.* at 9-10.) Investigators were also directed to request a recent drug utilization report from the pharmacy, showing the top twenty-five controlled substances by quantity dispensed²⁸ and six to twelve months of usage data by month. (*Id.* at 10.)

Other important factors included: the volume of controlled substances ordered; the percentage of transactions that did not include some form of third-party payment; the percentage of Schedule II controlled substances dispensed relative to all controlled substances; the percentage of controlled substances dispensed relative to non-controlled substances; and whether the pharmacist seemed to understand his or her responsibility to dispense controlled substances only for legitimate purposes. (Feb. 6 Moné Decl. ¶ 21.)

During the report preparation phase, the investigator was directed to analyze the information collected, to formulate a recommendation to the Director of Investigations, and to prepare a final report in the pre-approved memo format. (On-Site Investigations, Dec. 22, 2008, at 11.) At a minimum, the report would indicate whether the pharmacy posed a significant risk of diversion. (*Id.*) In the usual case, a site visit was to be completed within thirty days of assignment and a final report was to be submitted to the Director of Investigations within ten days of the visit, but priority cases could be assigned shorter time frames. (*See id.* at 4.)

The SOPs required the Director of Investigations to “monitor the progress of cases and provide guidance and direction as necessary to develop and move the case to a successful conclusion.” (*Id.* at 5.) The Director was required to “conduct a thorough, final review of each case and make a determination whether the case is complete” (*Id.* at 12.) Initially, the first Director of Investigations, Steve Morse, reviewed every site visit report, but he later required the investigators to rate each customer as a high, medium, or low risk of diversion, and then he reviewed customers that the investigators identified as medium or high risk. If an on-site investigation was conducted in response to a threshold event, Morse, a pharmacist, would usually make the decision whether to adjust the customer’s threshold.

²⁷ Revised SOPs issued in November 2009 included four additional factors: one employee responsible for ordering, monitoring, and invoicing products; a high number of customers compared to their peers; for practitioner offices, whether the practitioner dispensed directly to the public; and a lack of auditing processes surrounding the purchases. (On-Site Investigations, Nov. 5, 2009, at 7.)

²⁸ Revised SOPs issued in November 2009 required drug utilization reports showing all controlled substances by quantity dispensed or administered. (On-Site Investigations, Nov. 5, 2009, at 8-9.)

c. Reporting Suspicious Orders

The CSA requires distributors to “design and operate a system to disclose . . . suspicious orders of controlled substances” and inform the appropriate DEA Field Division Office of any suspicious orders. 21 C.F.R. § 1301.74(b). According to the § 1301.74(b), “[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b). The Company issued SOPs and conducted training in December 2008, explaining the obligation to report suspicious orders and providing the definition of suspicious orders set out in C.F.R. § 1301. (Regulatory Notification of Suspicious Orders and/or Suspension of Sales of Scheduled /List 1 Substances (hereinafter, “Regulatory Notification”), Dec. 22, 2008, at 1; *see also* Joint Legal QRA Meeting, at 5.) The SOPs described the necessary information and provided form memos to be used in reporting suspicious orders to the DEA and State boards of pharmacy. (Regulatory Notification, at 4-8.) The pharmacists in the anti-diversion group determined which orders should be deleted and not filled and which customers to report to the DEA as suspicious based on the language of § 1301.74(b), and their knowledge and expertise.

4. Training

The Company provided anti-diversion training to distribution center employees, including all personnel with access to controlled substances and their supervisors, as well as the pharmaceutical sales force and any personnel involved in compliance-related functions. (Morford Decl. ¶ 8; Quintero Decl. ¶ 8.) The Company required thousands of employees across a variety of departments²⁹ to take the Anti-Diversion – Know Your Customer training module, which covered such topics as: types of diversion; the Company’s approach to combating diversion and the purpose of the anti-diversion measures; reporting suspected violations; screening new customers; monitoring existing customers; investigating suspected diversion; and taking corrective action once diversion was detected. (*See* Anti-Diversion KYC WebX Training Module, at 8, 18-25, 28, 31, 35-37.) Employees were required to score 100% on the post-training test to earn a certificate of completion. (Anti-Diversion KYC Web-X Training Module, at 5.) The module was administered through the “MyLearning” program, which automatically assigned computer-based training to employees based on their job titles, and sent electronic notifications and reminders to employees about required training. Any training not completed by the due date would be included on a past due list and the employee’s supervisor would be notified.

In addition to computer-based training, there were also periodic live presentations regarding the anti-diversion system. (*See, e.g.*, Supply Chain Integrity, Michael A. Moné, 2010 (discussing the SOM system and indicators of diversion); Quality and Regulatory Affairs: Overview of Anti-Diversion Program, 2011 (discussing the electronic monitoring system and KYC procedures).)

²⁹ The departments included Sales (Medical and Pharmaceutical), Operations, Human Resources, Finance, Customer Service, IT, Facilities, and Real Estate.

a. Training of Sales Personnel

In addition to the Anti-Diversion Training Module, the sales force received supplementary training on the Know Your Customer procedures and the electronic monitoring system. (*See, e.g.,* Anti-Diversion: It's Everyone's Responsibility, Cardinal Health National Sales Conference Presentation, Michael A. Moné, 2008, at 3-5.) The salespeople were also trained on indicia of diversion, such as long lines in the pharmacy, out-of-state customers, and large percentages of controlled substance sales that were not reimbursed by insurance or other health programs. (Giacomin Decl. ¶¶ 9-10.) A ready reference document was provided to help salespeople identify signs of diversion.

The sales force received anti-diversion training from QRA and from their own dedicated training staff. Moné also spoke each year at the annual sales conference on compliance issues and trends in diversion. (Giacomin Decl. ¶ 9.)

b. Training of QRA Personnel

Pharmacists, investigators, analysts, distribution center employees, and compliance officers all received anti-diversion training focused on their specific job functions. Each of the pharmacists was trained on the Company's anti-diversion policies and procedures, including the procedures for reviewing customers and threshold events. Pharmacists also received "on-the-job" training focused on monitoring existing customers for signs of diversion.

The investigators received one-on-one training with the Director of Investigations when they started with Cardinal Health. Because the investigators already had investigative experience, the training focused on pharmacies and drugs, including warning signs to look for when evaluating a pharmacy, as well as different types of drugs and standard nomenclature. The investigators were also trained on the Company's anti-diversion system and procedures, and on setting the proper "tone" during site visits. In addition, the investigators and pharmacists attended conferences of the National Association of Drug Diversion Investigators ("NADDI"), the National Association of State Controlled Substances Authorities, and the American Pharmacists Association. (Feb. 6 Moné Decl. ¶ 5.)

Analysts received training that included how to interpret and verify information provided by customers and how to research and gather information on customers. Analysts also received instruction on the types of information that should be brought to the attention of their superiors in QRA.

Distribution center employees underwent extensive training on anti-diversion and other compliance-related issues. Employees in the cage and vault received additional anti-diversion training. All distribution center employees were provided with a wallet card listing indicators of diversion. Compliance officers were responsible for administering training on any relevant changes to the procedures, and would conduct periodic audits to ensure that all personnel had undergone the required training.

New compliance officers typically underwent week-long training at the Company's corporate offices, which included training on the anti-diversion policies and procedures.

Compliance officers also attended annual meetings at the corporate offices, where they received additional training on the Company's anti-diversion system. The topics discussed at the annual meetings included the relevant regulations and the obligation to report suspicious orders, the implementation of the electronic monitoring system and changes to the system, sample threshold event exercises, and trends in diversion, among others. (*See, e.g.,* DEA & Boards of Pharmacy Priorities, QRA Compliance Officer Annual Meeting, Michael A. Moné and Martha Russell, June 9, 2010; QRA – SOM Update 2011, Michael A. Moné, June 29, 2011.)

5. DEA Inspections

As part of the 2008 MOA, the DEA visited Cardinal Health headquarters in Dublin in early 2009 to review the new anti-diversion system, and conducted "compliance reviews" at five distribution centers. (*See* 2008 MOA at 5-6.) The DEA indicated initially that it found the controls in place at one distribution center, the facility located in Valencia, California, to be "unsatisfactory," but the Company rectified the issues and the DEA did not bring any formal proceedings regarding the facility. (*See* Letter from Larry P. Cote to Mark Hartman, Mar. 16, 2009; Letter from Jodi L. Avergun to Wendy H. Goggin and Larry P. Cote, Mar. 25, 2009; *see also* Chief Compliance Officer Q3 Update, Craig Morford, May 2009, at 4.)

The DEA also conducted routine cyclical inspections at Cardinal Health distribution centers in the years following the 2008 MOA. The DEA did not issue any negative findings regarding the anti-diversion measures in place at any distribution center in the years leading up to the October 25, 2011 Warrant for Inspection for the Lakeland facility.³⁰ In general, notes taken by Cardinal Health personnel who were present during the inspections indicated that the DEA inspectors were satisfied with the anti-diversion procedures that they reviewed. (*See generally*, DEA Cyclical Inspection Notes.) These notes were forwarded to management within QRA, and the Company informed the Board that the inspections had been "successful" and that there were no negative findings regarding the SOM system. *See infra* Part V.

For example, during the May 2009 inspection of the Aurora, Illinois facility, Cardinal Health personnel reviewed the SOM system with the DEA inspectors and the list of "red flags" used when reviewing orders. (DEA Cyclical Inspection Notes, at 3.) Notes taken by a Cardinal Health employee who was present during the inspection state that the DEA inspectors told facility personnel during the exit interview to "keep up the good work." (*Id.*) In an email to a Vice President of QRA regarding the final day of the inspection, a regional director who was present for the inspection noted, "[w]e heard from them during the closeout many many times 'We have nothing for you, you guys are perfect.'" (*Id.* at 2.) Similarly, during the August 2010 inspection of the Knoxville, Tennessee facility, during which the facility's compliance officer

³⁰ In September 2009, the DEA conducted a cyclical inspection of the distribution center located in Hudson, Wisconsin. (*See generally*, DEA Cyclical Inspection Notes, at 33-37.) The inspectors commented during the inspection that certain orders that the Hudson facility filled should have been reported as suspicious, but there were no negative findings issued and, according to the notes from the inspection, the inspectors indicated that they were generally satisfied with the inspection. *Id.* at 37.

In Fall 2011, the DEA sent letters of admonition regarding certain operational compliance issues for three facilities, relating specifically to record keeping and the fact that one facility shipped controlled substances to a customer's new address that had not yet been registered with the DEA.

gave a short explanation of the Company's "identify, block, report" mantra for suspicious orders, one of the inspectors remarked during the exit interview, "everything is peachy." (*Id.* at 29.)

In May 2010, two DEA field inspectors conducted a two-day inspection of the Company's Lakeland, Florida distribution center.³¹ (*Id.* at 18.) The inspection included a review of the facility's security system, ARCOS/CSOS³² protocol, specific customer order history, inventory reports and records, and anti-diversion training. (*Id.* at 18-19.) The distribution center personnel also gave a presentation to the DEA inspectors on the SOM system, which lasted over an hour and included a power point presentation. (DEA Cyclical Inspection Notes, at 18; Butler Decl. ¶ 19.) The DEA inspectors stated that they needed to see the SOM system in action because a major purpose of the inspection was "to ensure that Cardinal Health was doing what they had agreed to in the [2008] MOA and that the process was working the way they said it did." (*Id.*) The inspectors asked to review the SOM process from account set-up to deactivation, including examples of all documents and forms used during the process, for seven specific customers. (*Id.* at 19.)

During the review of the seven customers, facility personnel provided the inspectors with the Schedule II and Schedule III controlled substance sales for those customers for a two-month period, noting that the Company had previously discontinued controlled shipments to one of the registrants in September 2009. (*Id.* at 19.) The DEA inspector reviewed the documentation for this particular customer, continually noting that reviewing the specific records and documentation would verify whether the SOM system was working. (*Id.*) According to the notes recorded by a Company employee, the DEA inspector indicated that "[t]he documentation reviewed verified the process was working as presented." (*Id.*)

The inspection also reviewed the facility personnel's knowledge of the ARCOS and CSOS systems. (*Id.* at 18.) Although the ARCOS/CSOS portion of the inspection was a new component not previously reviewed by DEA, the notes indicate that the inspectors were impressed with the employees' knowledge of the relevant process. (*Id.* at 18, 20.)

During the final portion of the inspection, the inspectors asked the distribution center Compliance Officer about the various training efforts for employees. (*Id.* at 20.) The Compliance Officer noted that everyone who worked in the facility was required to undergo training that included "DEA general awareness, anti-diversion, and suspicious order monitoring," and that employees who had unsupervised access to the cage/vault area were required to complete Cage/Vault certification training and score 100% on the post-training test.

³¹ The DEA also visited the Lakeland facility in early 2009, in accordance with the 2008 MOA. Personnel who were present for the inspection, including a Regional Director of Quality, reported that the DEA agents complimented the facility's systems, and that no changes needed to be made in response to the inspection.

³² ARCOS stands for Automation of Reports and Consolidated Orders System and is a system used by DEA and other governmental authorities to gather information from drug manufacturers and distributors regarding inventories, acquisitions, and dispositions of controlled substances. (*See* <http://www.dea diversion.usdoj.gov/arcos/faq.htm>.) CSOS stands for Controlled Substance Ordering System and is a DEA program that allows for electronic ordering of controlled substances. (*See* <http://www.deaecom.gov/about.html>.)

(*Id.*) The DEA inspector seemed surprised and impressed to learn that a 100% score was required. (*Id.*; Butler Decl. ¶ 18.) The DEA inspector also seemed surprised to learn that there was mandatory annual follow-up training on the cage/vault certification, SOM system, anti-diversion and DEA general awareness. (*Id.*)

At the end of the inspection, the DEA inspectors advised facility personnel that their inspection resulted in no negative findings or comments and that the Lakeland facility was in compliance with DEA regulations and the terms of the MOA. (Butler Decl. ¶ 22; DEA Cyclical Inspection Notes, at 20.) The inspectors indicated that the SOM presentation was “great” and that they were able to verify actual compliance by tracing customer activity through account set up to deactivation. (DEA Cyclical Inspection Notes, at 20.)

In July 2009, the DEA conducted an inspection of a distribution center in Peabody, Massachusetts. The inspector suggested to facility personnel, and then to Moné via telephone, that Cardinal Health should conduct due diligence on chain stores in the same manner as it did for independent pharmacies, including by conducting site visits of chain stores.³³ (*See* Declaration of Joseph Rannazzisi, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 10, 2012), ¶ 59.) Soon after, Moné spoke with Barbara Boockholdt, Chief of the Regulatory Section in the DEA’s Office of Diversion Control, and relayed the conversation with the inspector and reminded Boockholdt that Cardinal Health coordinated with the chain pharmacies’ corporate loss prevention departments regarding orders of concern and did not conduct on-site investigations of chain pharmacies.³⁴ (Apr. 23 Moné Decl. ¶ 8.) Based on the fact that Boockholdt made no disagreement and on his prior experiences with Boockholdt, Moné concluded that the DEA did not object to Cardinal Health’s procedures for chain pharmacies. (Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 20, 2012) (“Feb. 20 Moné Decl.”), ¶ 15.) In November 2009, Boockholdt indicated that Cardinal Health should exercise the same level of oversight with respect to chain pharmacies as it did with independent pharmacies. (Apr. 23 Moné Decl. ¶ 9.) The Company explained its method of coordinating its diligence efforts with the chains’ loss prevention teams in addition to conducting its own review of the ordering data for chain stores, and there were no further comments from the DEA about the issue. (*Id.*)

³³ The inspector also commented on the fact that records for certain chain pharmacies were not available at the facility, and Moné explained to the inspector that such records are maintained at Cardinal Health’s headquarters in Dublin. (Supplemental Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 12, 2012) (“Feb. 12 Moné Decl.”), ¶ 7.)

³⁴ Moné had previously discussed this with Boockholdt during the DEA visit to Cardinal Health’s headquarters in Dublin in early 2009, and neither Boockholdt nor any of the other DEA personnel present during that meeting raised any objections to the Company’s procedures for chain pharmacies. (Supplemental Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 23, 2012) (“Apr. 23 Moné Decl.”), ¶ 3.)

V. COMMUNICATIONS WITH THE BOARD AND AUDIT COMMITTEE REGARDING ANTI-DIVERSION MEASURES

The Board and Audit Committee³⁵ received regular and extensive updates regarding the anti-diversion system. Craig Morford provided annual compliance reports to the Board each August and annual regulatory reports to the Audit Committee (or the full Board) each November. Morford also provided the Audit Committee and the Board with updates on compliance and regulatory issues as warranted, either at the quarterly meetings or via communications between the quarterly meetings.³⁶ The Board was also provided with updates as part of the Company's Enterprise Risk Management system, which informs the Board about risks the Company is facing, including enforcement actions and compliance issues. (*See, e.g.*, Enterprise Risk List, May 2011.) In addition, Morford updated the Audit Committee and the Board on an as-needed basis.³⁷ The following is a summary of some specific communications and materials relating to the Company's anti-diversion measures that were provided to the Board and the Audit Committee between 2007 and 2012.

In August 2007, Walsh provided the Board with a presentation that highlighted the creation of the anti-diversion policies. (Annual Program Review, Ethics and Compliance, Dan Walsh, Aug. 2007, at 4.) Two months later, the Audit Committee received a report listing issues and initiatives for 2007, including reengineering systems and updating practices for controlling Schedule 3 drugs. (Quality & Regulatory Affairs Update, Gary Dolch, Oct. 2007, at 6.) In November 2007, the Audit Committee was informed that the Company had developed a web-based training module and administered anti-diversion training to more than 2,300 employees. (Chief Ethics and Compliance Officer Update, Daniel J. Walsh, Nov. 6, 2007, at 3, 6.)

In January 2008, the Audit Committee learned that the Company engaged "outside counsel and their retained anti-diversion experts to conduct an expansive review of the historic and current anti-diversion practices at all of the Company's distribution facilities." (Report on Lawsuits and Claims, Ivan K. Fong, Jan. 18, 2008, at 7.) In addition, the Audit Committee learned that the Company had accelerated the due diligence being performed on customers that were top purchasers of certain controlled substances, established ordering limitations for those substances, and began implementation of a computerized order monitoring and control system to assist in preventing diversion. (*Id.*)

In advance of the January 31, 2008 Board meeting, the Board was informed that in reacting to the "flurry of actions from the DEA," the Company took immediate action against a

³⁵ The Audit Committee is appointed by the Board to assist the Board with, among other things, the Company's compliance with legal and regulatory requirements and the Company's processes for assessing and managing risk. (*See* Audit Committee Charter, Nov. 2, 2012, at 1.) The Audit Committee meets as often as it deems necessary, but is required to meet at least once per quarter. (*Id.*)

³⁶ Before Morford joined the Company, the Board received compliance and regulatory updates from his predecessor, Daniel Walsh, as well as Ivan Fong, the Chief Legal Officer and Secretary, and Jeff Henderson, the Chief Financial Officer.

³⁷ When a new director joined the Board, Morford and Steve Falk, General Counsel, would provide that director with an overview of the Company's anti-diversion program. Gilberto Quintero also provided updates to the Board, and provided the Board with an overview of the entire anti-diversion system.